

### Remarks

In view of the following remarks, reconsideration and further examination are respectfully requested.

Claims 9 and 14 have been amended with this reply. No claims have been added. Claims 10 and 16 have been canceled. Thus, claims 1-9, 11-15, and 17-22 are currently pending and under consideration.

### Claim Objection

In item 1 of the Office Action, claim 14 was objected to due to an informality. Claim 14 has been amended so as to obviate this objection. It is respectfully requested that this objection be withdrawn.

### Independent claim 1

#### *Mitchen*

In item 3 of the Office Action, independent claim 1 was rejected under 35 USC 102(b) as being anticipated by Mitchen (US No. 5,014,718). Applicants respectfully traverse and submit that Mitchen fails to disclose or suggest all of the features recited in claim 1. For example, Mitchen fails to disclose “the expression surface having at least two opposing compression surfaces with a negative sigmoidal shape to enhance expression of body fluid from the incision” as recited in claim 1.

As mentioned in the present application, when a flat expression member is pressed against a finger, uneven pressure is applied around the incision site. Specifically, the expression member blocks the flow of blood in the arteries along the finger, while at the same time allows blood to escape from the sides of the finger. The expression surface according to the present application is shaped to apply a generally even force against the body part when expressing body fluid from the incision. In particular, the expression surface described in the present application has a negative sigmoidal shape and relief notches configured to receive a body part, such as a finger. As those of ordinary skill in the art would understand, a negative sigmoidal shape generally has an S-shaped profile, and more particularly, the negative sigmoidal shape includes two arc-like segments having opposite curvatures that connect to each other at a point of tangency. That is, one arc-like segment is convexly curved and the other is concavely curved. In

other words, the overall negative sigmoidal shape is similar to a graph of a cosine function between 0 and 180 degrees, where the curvature between 0 and 90 degrees behaves similarly to the outermost arc-like segment, and the curvature between 90 and 180 degrees behaves similarly to the innermost arc-like segment. It was discovered that the negative sigmoidal shape of the expression surface in conjunction with the relief notches was particularly effective in expressing body fluid. The relief notches prevent the cutoff of the circulatory flow of blood in the arteries along the finger, thereby permitting an even greater blood flow from the incision.

As should be appreciated, the collapsible cap 14 of Mitchen does not have a negative sigmoidal shape. That is, the collapsible cap 14 does not have a cross-sectional profile in which two arc-like segments having opposite curvatures connect to each other to form an expression surface. With reference to FIGS. 2 and 4 of Mitchen, although arguably the cup-shaped top 15 of the cap 14 has an arc-shaped lip, the lip is not connected to another arc-shaped segment with an opposite curvature. As can be seen, the outer radial rim of the cup-shaped top 15 is flat, and the wall inside the lip is similarly flat. Consequently, the collapsible cap 14 in Mitchen does not have a negative sigmoidal shape.

As another example showing why Mitchen does not anticipate claim 1, Mitchen fails to disclose “the expression cap defining a relief notch between the compression surfaces, the relief notch being sized to receive the finger to permit the compression surfaces to first contact the finger when the expression surface is pressed against the finger,” as recited in independent claim 1. As discussed in the present application, the relief notches are shaped to generally conform to the shape of a finger or to other body parts. The relief notches prevent the cutoff of the circulatory flow of blood in the arteries of the finger, thereby permitting an even greater blood flow from an incision. In addition, the relief notches permit a generally even pressure to be applied against the skin, which in turn increases the amount of fluid expressed from an incision. In contrast, looking at FIGS. 2 and 4 of Mitchen, the collapsible cap 14 has a generally cylindrical shape and lacks any type of relief notch. By lacking a relief notch, as is clearly shown in FIG. 3, the lip of the cap 14 pinches or cuts off blood flow to the tip of the finger. Given that Mitchen fails to disclose all of the features recited in claim 1, such as the negative sigmoidal surface and the relief notch, Mitchen fails to anticipate claim 1. For these and other reasons, independent claim 1 and its dependent claims are allowable over Mitchen.

*Moerman*

In item 4 of the Office Action, independent claim 1 was rejected under 35 USC 102(e) as being anticipated by Moerman (US No. 6,706,049). In traversal, it is submitted that Moerman fails to disclose or suggest all of the features recited in independent claim 1.

For example, Moerman fails to disclose or suggest “the expression cap having an expression surface to express fluid from the incision, the expression surface having at least two opposing compression surfaces with a negative sigmoidal shape to enhance expression of body fluid from the incision” as recited in claim 1. As noted above, the negative sigmoidal shape enhances fluid expression from the incision. It should be recognized that the multi-contoured surface 22 illustrated in FIG. 4A of Moerman does not have a negative sigmoidal shape because the inner 26 and outer 24 radial portions are curved in the same direction. Although at column 5, lines 42-45 Moerman mentions “[a]lternatively, the outer radial portion 24 can be convex or concave in curvature ... [and] ... the inner radial portion 26 is generally concave in curvature, but can also be linear or convex”, Moerman fails to expressly disclose an embodiment in which the outer 24 and inner 26 radial portions have opposite curvatures. Further, the negative sigmoidal shape is not inherent because it is not necessarily present in the multi-contoured surface 22 of Moerman. Specifically, it is quite conceivable (and quite likely from FIG. 4A) that the radial portions 24, 26 are curved in the same direction. As should be also appreciated, the pressure wings 82 in expression cap 80 do not have a negative sigmoidal shape. As can be seen in FIG. 10 of Moerman, the pressure wings 82 in Moerman are not two arc-like segments having opposite curvatures that connect to each other at point of tangency. In Moerman, a fingertip is placed inside the recess 87 that is defined by the pressure wings 82. Consequently, the radial outer portion 88A is not part of an expression surface because the outer portion 88A never contacts skin of the fingertip during expression.

Thus, given that Moerman fails to disclose all of the features recited in independent claim 1, it fails to anticipate claim 1 and its dependent claims. For this and other reasons, independent claim 1 and its dependent claims are allowable over the references of record.

Independent claim 9

Independent claim 9 has been amended to incorporate the features of dependent claim 10, and dependent claim 10 has been canceled. It is submitted that claim 9, as currently amended, is allowable over the references of record.

*Mitchen*

In item 3 of the Office Action, dependent claim 10 (now claim 9) was rejected under 35 USC 102(b) as being anticipated by Mitchen. Applicants respectfully traverse and submit that Mitchen fails to disclose or suggest all of the features recited in claim 9, as currently amended. For example, Mitchen fails to disclose “wherein the expression surface has a negative sigmoid shape” as recited in claim 9. As discussed above, the collapsible cap 14 in Mitchen does not have a negative sigmoid shape. In another example, Mitchen fails to disclose “the expression surface defining a relief notch” as recited in claim 9. The collapsible cap 14 in Mitchen is cylindrical and lacks any type of notch. Given that Mitchen fails to disclose all of the features recited in claim 9, it fails to anticipate independent claim 9 and its dependent claims.

*Moerman*

In item 4 of the Office Action, dependent claim 10 (now claim 9) was rejected under 35 USC 102(e) as being anticipated by Moerman. In traversal, it is submitted that Moerman fails to disclose or suggest all of the features recited in independent claim 9, as currently amended. For example, Moerman fails to disclose “wherein the expression surface has a negative sigmoid shape” as recited in claim 9. Thus, given that Moerman fails to disclose all of the features recited in independent claim 9, it fails to anticipate claim 9. As noted before, the multi-contoured surface 22 illustrated in FIG. 4A and the expression cap 80 in FIG. 10 of Moerman do not have a negative sigmoidal shape. For these and other reasons, independent claim 9 and its dependent claims are allowable over the references of record.

### Independent claim 15

#### *Mitchen*

In item 3 of the Office Action, independent claim 15 was rejected under 35 USC 102(b) as being anticipated by Mitchen (US No. 5,014,718). Applicants respectfully traverse and submit that Mitchen fails to disclose or suggest all of the features recited in claim 15. For example, Mitchen fails to disclose “providing a sampling device that has an expression surface with at least two opposing compression surfaces that have a negative sigmoidal shape and a relief notch defined between the compression surfaces that is shaped to generally conform to a body part” and “expressing body fluid from the incision by exerting pressure between the body part and the expression surface” as recited in claim 15. As previously discussed, the collapsible cap 14 in Mitchen does not have a negative sigmoidal shape and does not have a relief notch, and therefore, the cap 14 is unable to express fluid in the manner as recited in claim 15. Given that Mitchen fails to disclose all of the features recited in claim 15, it fails to anticipate independent claim 15 and its dependent claims.

#### *Moerman*

In item 4 of the Office Action, independent claim 15 was rejected under 35 USC 102(e) as being anticipated by Moerman. From the previous discussion, it should be recognized that Moerman fails to anticipate claim 15 because for example Moerman fails to disclose “at least two opposing compression surfaces that have a negative sigmoidal shape” and therefore does not express fluid in the manner as recited in claim 15. To reiterate, Moerman fails to disclose, either expressly or inherently, an expression surface that has a negative sigmoidal shape. For this and other reasons, independent claim 15 and its dependent claims are allowable over the references of record.

### Concluding Remarks

It should be understood that the above remarks are not intended to provide an exhaustive basis for patentability or concede the basis for the rejections in the Office Action, but are simply provided to overcome the rejections made in the Office Action in the most expedient fashion.

In view of the above amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and an early notice of allowance is earnestly

solicited. If after reviewing this amendment the Examiner feels that any issues remain which must be resolved before the application can be passed to issue, the Examiner is invited to contact the undersigned representative by telephone to resolve such issues.

Respectfully submitted,

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